PATENT SPECIFICATION 1,130,593

DRAWINGS ATTACHED.

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COMPLETE SPECIFICATION

Injection Syringe with Two Coaxial Cylindrical Chambers.

We, NOVO TERAPEUTISK LABORATORIUM A/S, a body corporate organised under the laws of Denmark, of Fuglebakkevej 115, Copenhagen, Denmark, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The invention relates to an injection syringe with two coaxial cylindrical chambers, the first of which is defined by an outer cylinder body and a foremost tubular plunger or piston displaceably located therein, while the second chamber is defined by the tubular plunger and a hindmost plunger or piston displaceably located therein, said chambers being interconnected by means of one or more connecting ducts or passages provided in the foremost plunger, said duct or ducts being normally closed by means of a closing means, which is arranged to unblock the ducts by the creation of an overpressure in the chamber in the foremost plunger.

Such injection syringes with two separate chambers are used in particular for the storage and injection of medicaments consisting of two ingredients, e.g. a solid substance and a solvent therefor, which are unstable when ready-mixed. In an injection syringe of the said nature the two ingredients can be placed each in its own chamber and be mixed immediately before the use or the injection.

In a known injection syringe of the type referred to, the outer cylinder body as well as the foremost tubular plunger or piston are provided with external finger grips, and said first cylindrical chamber is intended for the storage of a powdered, solid substance, while the second chamber in the tubular plunger is intended to contain a liquid solvent for the solid substance. When this known syringe is to be used, the index finger and the long finger are placed on the finger grips on the tubular plunger and by means of the thumb the hindmost plunger is pushed inwardly into the second chamber located in the tubular plunger and containing the solvent. The excess pressure which thus arises in the said second chamber causes the closing means to uncover the connecting ducts, which are provided in the foremost tubular plunger and connect the two chambers of the injection syringe. By continuing to push the hindmost plunger inwardly into the said second chamber, the solvent will be forced therefrom and into the first chamber, which contains the solid substance. When the solvent has been introduced into the first chamber in this way, the solid substance is dissolved in the solvent, and the process of dissolution may be hastened by shaking. The injection syringe is now provided with a cannula, whereafter the index and long fingers are moved forward so as to rest on the finger grips on the outer cylinder body, and if an inward pressure is now again applied to the said hindmost plunger by means of the thumb, the tubular foremost plunger will be moved inwardly into the first chamber in the cylinder body, which chamber now contains the

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mixed medicament, whereby the latter will be expelled through the cannula.

When, in the known syringe, the solvent is forced through the connecting duct or ducts from the second into the first chamber, an over-pressure will arise in the said first chamber, tending to drive the tubular foremost plunger out of the cylinder body. As the hand manipulating the syringe during the mixing process has got hold of the two plungers only, it is necessary to take hold of the cylinder body with the other hand, if the tubular plunger is to be prevented from being driven completely out of the cylinder body. Furthermore, by said known injection syringe, which is provided with finger grips on the cylinder body as well as on the tubular plunger, there is a risk that the user of the syringe erroneously starts to take hold of the syringe in such a way that the index and long fingers rest against the finger grips on the cylinder body. The closing means, which in the known construction consists of a hood or cap provided on a tubular neck on the foremost end of the tubular plunger, must necessarily be so firmly seated, if premature mixing of the substances stored in the two chambers is to be avoided, that it is not realised until a rather substantial excess pressure has been created in the liquid solvent, which is stored in the second chamber in the tubular plunger. Consequently, the aforesaid erroneous operation of the known syringe may have the effect that during compression of the air within the first chamber containing the solid substance the tubular foremost plunger is moved forward to such an extent before the closing member is released that the closing means or the hood will already be in abutment against the solid substance in the first chamber, whereafter the release of the hood or closing member is made quite impossible.

The invention has for its object to provide an injection syringe of the said type, which is not subject to the said drawbacks, as it is intended to be operated with one hand and to preclude the possibility of erroneous operation.

The injection syringe according to the invention is characteristic in that on the said first plunger releasable locking means are provided, said locking means being adapted to engage the wall of the outer cylinder body in the initial position of said plunger and thus to lock the foremost plunger from moving forward in relation to the cylinder body, and that on the said hindmost plunger releasing means is provided being adapted to engage and release the locking means after a forward displacement of the hindmost plunger from its initial position.

When the syringe according to the invention is to be used, it is only necessary to take hold of the outer cylinder body, which may be provided with finger grips, e.g. with the index and long fingers, and thereupon to force the said hindmost plunger inwardly by means of the thumb. During at least the first part of this movement, the said locking means bar the tubular foremost plunger from moving forward, for which reason an excess pressure will arise in the second chamber in the tubular plunger. This excess pressure will release the closing means, so that a connection is established through the connecting ducts in the tubular plunger between the second and first chambers, whereupon liquid solvent will be forced from the second chamber into the first chamber, wherein, as mentioned, a powdered, solid substance may be stored. During this mixing operation only a limited over-pressure may arise in the foremost chamber in the cylinder body, as the tubular foremost plunger, whose area is larger than that of the hindmost plunger, may freely move rearwardly corresponding to the increase in the quantity of substance in the first chamber. When the solvent has been introduced into the foremost chamber in this way, the dissolution of the solid substance may be hastened by shaking the syringe, as in the case of the known syringe, and after the syringe has been provided with a cannula, or connection has been established with a cannula provided beforehand on the syringe, it is possible without changing the hold on the same to carry out an injection by forcing the hindmost plunger still more inwardly, as the releasing means on said plunger is so arranged that at this point they have already released the locking means, so that the tubular foremost plunger can be forced forward together with the hindmost plunger.

It will be seen that there is no possibility of operating the syringe according to the invention erroneously, as the syringe can be taken hold of in the same way during the mixing operation as well as during the very injection. It will furthermore be seen that in the case of the syringe according to the invention there is no risk that the rearward movement of the tubular plunger during the mixing operation leads to the coming apart of the components of the syringe, as in the case of the syringe according to the invention the same hand takes hold of the two outermost parts of the syringe, i.e. the cylinder body and the hindmost plunger, respectively, during the mixing operation as well as during the injection.

According to the invention the locking means may have the form of one or more radially movable and outwardly resiliently biassed pawls, which in the initial position of the foremost plunger may engage substantially radially directed abutment faces

provided on the inner side of the cylinder body, and the releasing means may completely or partially form a cylindrical skirt, which is coaxial with the plungers and the cylinder body and has such a diameter and wall thickness that it may surround the foremost tubular plunger but move clear of the radially directed abutment faces. The said pawls only hinder a premature forward movement of the tubular foremost plunger, but not a backward movement, which, as mentioned, may be desirable during the mixing operation. When the hindmost plunger has been forced forward to such an extent that substantially all of the liquid solvent has been pressed into the first chamber, the foremost and hindmost plungers will have performed such a movement in relation to each other that the cylindrical skirt on the hindmost plunger extends over the pawls and keeps them pressed inward, so that they can no longer engage the abutment faces on the cylinder body and prevent the forward movement of the tubular plunger.

When the foremost tubular plunger is of a relatively elastic material, e.g. a plastics material, a particularly simple and cheap construction of the pawls is attainable, as according to the invention each pawl may be formed of a tongue, cut from the wall of the tubular plunger, the free end of said tongue facing forward and on the outer side of which tongue a wedge-shaped cam is formed whose thickness increases in forward direction, and which at the free end of the tongue forms a radially outwardly protruding shoulder.

It is essential that the sterility of the substances contained in a syringe of the said type is preserved during storage as well as during use. However, on account of the rearward movement of the tubular foremost plunger during the mixing operation there may sometimes be a risk that the medicament in the syringe thereby comes into contact with infected parts of the internal wall of the cylinder body. According to the invention, however, this can be avoided in that the radial abutment faces may be formed by a preferably annular recess in the cylindrical inner wall of the cylinder body, and in that the cylindrical skirt on the hindmost plunger may have an outer diameter which is substantially equal to the inner diameter of the cylinder body. In this case the cylindrical skirt will form a tight plug in the entrance to the annular space between the inner wall of the cylinder body and the hindmost part of the tubular foremost plunger. Thus, once sterilized, the inner wall of the cylinder body may keep its sterility during storage as well as during use.

As mentioned in the foregoing in connection with the known construction, the closing member may consist of a hood or cap, which is provided on a tubular neck on the foremost end of the tubular plunger, and which is forced off this tubular neck when a substantial over-pressure arises in the second chamber in the tubular plunger. The hood will thus lie loose in the first chamber and may consequently obstruct the connecting duct or ducts to the cannula. Such a loose hood may furthermore make it impossible to press the tubular plunger home and thus prevent a complete discharge of the medicament in the syringe. According to the invention, the said drawbacks can be avoided in that the closing means for the connecting ducts arranged in the first plunger may have the form of a hood or cap made of an elastic material, e.g. rubber, the cylindrical skirt of said hood providing a seal between the tubular foremost plunger and the inner wall of the cylinder body, and in that a projecting head arranged on the foremost end of the foremost plunger makes sealing engagement with a hole in the end wall of the hood. When, in the case of such a construction, a substantial excess pressure arises in the second chamber, the end wall of the hood will be forced forward so that it is "unbuttoned" from the projecting head, while the skirt of the hood will remain in place between the outer wall of the tubular plunger and the inner wall of the cylinder body. The solvent from the second chamber may now flow into the first chamber through the hole in the end wall of the hood. As the skirt of the hood is firmly held between the cylinder body and the tubular plunger, the hood will not be able to move uncontrollably within the first chamber, as in the case of the known construction.

The invention will be explained in more detail hereinafter, reference being made to the accompanying drawing, wherein

Fig. 1 shows an axial section through an embodiment of an injection syringe according to the invention in the condition, in which the syringe is stored,

Fig. 2 is a side view, partly in section, of the injection syringe shown in Fig. 1, after the hindmost plunger of the syringe, when use is being made of the latter, has been pushed forward to such an extent that the tubular formost plunger is released,

Fig. 3 is a side view, partly in section, of the injection syringe shown in Figs. 1 and 2, after a liquid solvent has been completely displaced by the said hindmost plunger from the chamber in the tubular foremost plunger,

Fig. 4 is a side view, partly in section, of the injection syringe shown in Figs. 1—3 with a cannula mounted thereon and after the injection has taken place, and

Fig. 5 is a plan view of the rearmost part of the tubular plunger.

The injection syringe shown in the drawing has an outer cylinder body 10, wherein there is displaceably mounted a tubular foremost plunger or piston 11. Within said plunger 11 there is displaceably mounted a hindmost plunger or piston 12, so that in the cylinder body 10 in front of the foremost plunger 11 there is defined a first or foremost cylindrical chamber 13, while within the tubular first plunger 11 in front of the hindmost plunger 12 there is defined a second or hindmost cylindrical chamber 14, Figs. 1 and 2. Within the first chamber 13 there is deposited some medicament 15, here shown in solid form, e.g. in powdered form, but which as a matter of course may also be in liquid form, and the second chamber 14 is substantially filled with a liquid solvent for the solid medicament 15.

In the front the cylinder body 10, which may be of glass, plastic material or any other appropriate material, is provided with a tubular neck 16, on which there is mounted a tubular, outer, conical cannula seat 17, the free edge of a cylindrical skirt 18 having been bent around an annular bead 19 on the neck 16. Between the cannula seat 17 and the free end of the neck 16 there is attached a sealing disc 20 of rubber, plastics material or the like elastic and penetrable material, see Figs. 1 and 4. Within the tubular cannula seat 17 there is displaceably mounted a perforation tube 21, which is pointed at its end facing the sealing disc 20. The cannula seat 17 and the perforation tube 21 protruding therefrom are normally protected by a protective hood 22, Figs. 1—3, which surrounds the skirt 18 tightly.

The tubular foremost plunger 11 is open at the back, but in the front it is closed by means of an end wall 23, wherein there is provided one or more through-going connecting ducts or passages 24. Normally, however, the said connecting ducts are covered and closed by a hood or cap 25, made of rubber, plastics material or the like elastic material, and placed on the foremost end of the tubular plunger 11, said cap being so shaped that its cylindrical skirt 26 provides a seal between the tubular plunger 11 and the inner wall of the cylinder body 10. The hood 25 is held in position on the tubular plunger 11 by means of the engagement of a bead-shaped internal projection 27 on the inner side of the skirt 26 with a corresponding recess provided in the outer cylindrical wall of the plunger 11, and furthermore by means of a through-hole 28 in the end wall of the hood 25 engaging and surrounding a projection 29 centrally provided on the end wall 23 of the tubular plunger 11, and on the extreme end of which projection there is provided a head 30, whose largest diameter is somewhat larger than the diameter of the hole 28, see Fig. 1. In the embodiment shown on the drawing, the seal between the cylindrical skirt 26 of the hood 25 and the inner wall of the cylinder body 10 is provided by means of sealing ribs 31 on the outer side of the skirt 26.

At its rearmost end, the tubular plunger 11 is provided with radially movable, outwardly resiliently biassed pawls 32. In the embodiment shown on the drawing, wherein the tubular plunger 11 is made of plastics material, each of the said pawls is formed of a tongue cut out of the plunger wall in the way shown in Fig. 5 by means of two axial and one transverse cuts, the free end of the tongue facing forward and a wedge-shaped cam 33 of which the thickness increases in the forward direction being provided on the outer side of the tongue so that the free end forms an outwardly protruding shoulder.

The hindmost plunger 12 is formed of a plunger body 34 of rubber, plastics material or the like elastic material, which is provided with sealing ribs 35 and screwed on to a plunger shaft 36, which at its rearmost end is appropriately attached to or formed integrally with a tubular body or a cylindrical skirt 37, which surrounds and is concentric with the plunger shaft 36. The cylindrical skirt 37 has an outer diameter which is substantially equal to the inner diameter of the cylinder body 10 and has a wall thickness such that it fits into the annular space between the cylinder body 10 and the tubular plunger 11 with a tight sliding fit.

The shown injection syringe is supplied from the factory, shipped, and stored in the condition shown in Fig. 1. The solid medicament 15 in the chamber 13 and the liquid solvent in the chamber 14 are completely separated from each other, as the hood 25 covers and closes the connecting ducts 24 in the end wall 23 of the tubular plunger 11. In storage condition, the tubular plunger 11 is in such a position that the outermost and foremost parts of the pawls 32 abut against a foremost, annular shoulder 38 on the inner side of the cylinder body 10 at the rearmost end thereof. The said shoulder constitutes the foremost end of an annular recess 39 at the inner side of the wall of the cylinder body 10. The hindmost plunger 12 is in such a position that the plunger body 34 just closes the rearmost end of the chamber 14 and that the foremost end of the cylindrical skirt 37 is positioned slightly to the rear of the cams 33 on the pawls 32.

When the injection syringe is to be used,

the syringe is gripped with one hand in such a way that the thumb comes to rest against the rearmost end 40 of the hindmost plunger 12 and the index and long fingers against the front side of finger grips 41, which in the shown embodiment are provided on the cylinder body 10. An inwardly directed pressure is now applied to the hindmost plunger 12. As, on account of the engagement of the pawls 32 with the shoulder 38, the tubular plunger 11 is prevented from moving in relation to the cylinder body 10, a substantial over-pressure will thereby arise in the hindmost chamber 14. This pressure will cause the end wall of the hood 25 to be "unbuttoned" from the projection 28, as the part of the hood surrounding the hole 28 will be pushed forward in front of the head 30, see Figs. 2—4, and as indicated on the drawing the solvent in the chamber 14 may now be pressed through the connecting ducts 24 and into the foremost chamber 13. The distance between the foremost end of the skirt 37 and the rearmost ends of the cams 33 in the initial position must be sufficient to ensure that the hood 25 has been unbuttoned from the projection 28 before the hindmost plunger 12 has been displaced through the said distance.

In Fig. 2 the invention syringe has been shown in a position wherein the hindmost plunger 12 has been pushed forward to such an extent that the foremost end of the cylindrical skirt 37 has passed some of the way over the cams 33. Thereby the pawls 32 have been forced radially inwardly to such an extent that they move clear of the shoulder 38, for which reason the tubular plunger 11 may now be moved freely in relation to the cylinder body 10. While an inwardly directed pressure is still applied to the hindmost plunger 12, the tubular plunger will probably at first move somewhat forward in relation to the cylinder body, the air in the chamber 13 being compressed, but the hindmost plunger 12 will also move forward in the chamber 14, so that still more solvent will be forced from the hindmost chamber 14 through the connecting ducts 24 to the foremost chamber 13. On account of the effective sectional area of the tubular plunger 11 being larger than that of the hindmost plunger 12, the tubular plunger will normally at least move to the rear in relation to the cylinder body 10 during this transfer of liquid solvent from the hindmost chamber to the foremost, and simultaneously the hindmost plunger 12 is forced forward so that the chamber 13 is sufficiently enlarged to contain the medicament 15 as well as the solvent therefore.

In Fig. 3 the parts of the injection syringe have been shown in the positions they occupy, when all of the solvent has been transferred from the hindmost chamber 14 to the foremost chamber 13. The syringe is now shaken in order to hasten the dissolution of the medicament 15 in the solvent. Thereupon the protective hood 22 is removed, and a cannula holder 42 with a cannula 43 is attached in known way to the cannula seat 17. When the cannula holder 42 is pushed over the cannula seat 17, the perforation tube 21 is pushed axially to the left, Fig. 4, so that the pointed end of the perforation tube penetrates the sealing disc 20 and enters the foremost chamber 13, which is thereby made to communicate with the bore of the cannula 43. After the air has been expelled in know way from the chamber 13 through the cannula 43, the injection syringe is ready for an injection. During the injection the hindmost plunger 12 is again driven forward, whereby also the tubular plunger 11 will be moved forward, so that the solution of medicament is driven out through the cannula 43. When the plungers have reached the positions shown in Fig. 4, substantially all of the solution of medicament has been expelled and the injection has been finished. The cannula 43 may now be removed, if desired, and sterilized for repeated use, while the rest of the syringe may be discarded.

It will be seen that in the operation of the injection syringe according to the invention it is not necessary to change the hold on the syringe, so that there is no possibility of erroneous operation. As the same hand grips the cylinder body 10 as well as the hindmost plunger 12 there is no risk of the components of the syringe coming apart during operation. Finally, it is noted that the foremost end of the cylindrical skirt 37 serves as a plug, which tightly closes the space between the outer surface of the tubular plunger 11 and the inner surface of the cylinder body 10 during storage of the syringe, so as to avoid contamination of surfaces which may come into contact with the liquid in the chamber 13 on account of the rearward movement of the tubular plunger.

It will be understood that various changes may be made in the embodiment shown in the drawing. By way of example it may be mentioned that the pawls 32 need not necessarily be integral parts of the tubular plunger 11, and that instead of having the form of a cylindrical skirt 37 the pawl releasing members may be an axially directed releasing finger for each pawl, as the plungers may be so controlled that they cannot be rotated in relation to the cylinder body 10. The contact surface for the pawls, which in the shown embodiment is formed of the shoulder 38, may alternatively be formed of cams protruding inwardly from the inner wall of the cylinder body 10. Furthermore, it should be mentioned that

the pawls 32 may be substituted by any form of suitable, releasable locking means which are capable of locking the tubular plunger 11 in relation to the cylinder body 10, until communication has been established between the foremost and hindmost chambers of the syringe, and thereafter of being released by suitable releasing means on the hindmost plunger 12 by an additional axial forward movement of same. The hood 25 may be substituted by any form of closing means designed to provide sealed separation of the foremost chamber 13 from the hindmost chamber 14 and to be released and establish connection between the said chambers when a suitable positive pressure is produced in the hindmost chamber 14. Finally, it should be mentioned that the injection syringe according to the invention may also be of the type which already in storage condition is provided with a cannula, which is protected by a protective hood in two parts, which parts are so connected to each other that the outermost part is released and falls off, so that the point of the cannula is uncovered, when the protective hood is displaced axially in the direction of the cylinder body of the syringe. In such case the finger grips 41 may be provided on the innermost part of the protective hood instead of on the cylinder body 10.

WHAT WE CLAIM IS:—

1. Injection syringe with two coaxial cylindrical chambers, the first of which is defined by an outer cylinder body and a foremost tubular plunger or piston displaceably located therein, while the second chamber is defined by the tubular plunger and a hindmost plunger or piston displaceably located therein, said chambers being interconnected by means of one or more connecting ducts or passages provided in the foremost plunger, said duct or ducts being normally closed by means of a closing means, which is arranged to unblock the ducts by the creation of an excess pressure in the chamber in the foremost plunger, characterized in that on the said foremost plunger (11) releasable locking means (32) are provided, said locking means being adapted to engage the wall of the outer cylinder body (10) in the initial position of the said plunger and thus to lock the foremost plunger from moving forward in relation to the cylinder body, and that on the said hindmost plunger (12) releasing means (37) is provided, being adapted to enegage and release the locking means after a sufficient forward displacement of the hindmost plunger from its initial position to build up the said excess pressure.

2. Injection syringe according to claim 1, characterized in that the locking means have the form of one or more radially movable and outwardly resiliently biassed pawls (32), which in the initial position of the foremost plunger engage substantially radially directed abutment faces (38) provided on the inner side of the cylinder body, and that the releasing means completely or partially form a cylindrical skirt (37), which is coaxial with the plungers and the cylinder body and has such a diameter and wall thickness that it may surround the foremost tubular plunger but move clear of the radially directed abutment faces.

3. Injection syringe according to claim 2, wherein the foremost tubular plunger is of a relatively elastic material, characterized in that each pawl is formed of a tongue, cut from the wall of the tubular plunger, the free end of said tongue facing forward and on the outer side of which tongue a wedge-shaped cam (33) is formed, whose thickness increases in forward direction, and which at the free end of the tongue forms a radially outwardly protruding shoulder.

4. Injection syringe according to claim 2 or 3, characterized in that the radial abutment faces are formed by a preferably annular recess (39) in the cylindrical inner wall of the cylinder body, and that the cylindrical skirt on the hindmost plunger has an outer diameter which is substantially equal to the inner diameter of the cylinder body.

5. Injection syringe according to any of claims 1—4, characterized in that the closing means for the connecting ducts (24) arranged in the foremost plunger has the form of a hood or cap (25) made of an elastic material, e.g. rubber, the cylindrical skirt (26) of said hood providing a seal between the tubular foremost plunger and the inner wall of the cylinder body, and in that a projecting head (30) arranged on the foremost end of the foremost plunger makes sealing engagement with a hole (28) in the end wall of the hood.

6. Injection syringe substantially as described and shown in the accompanying drawing.

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1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

Fig. 1

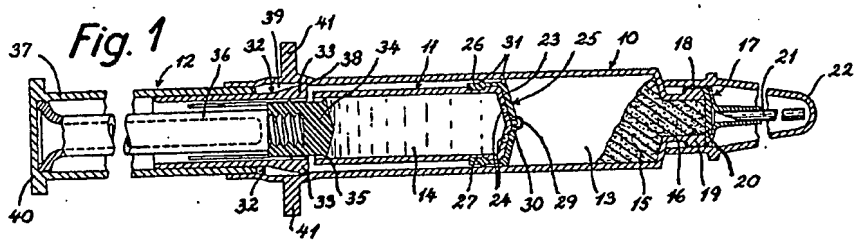

Fig. 2

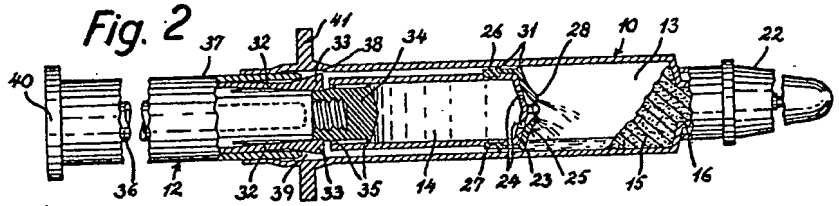

Fig. 3

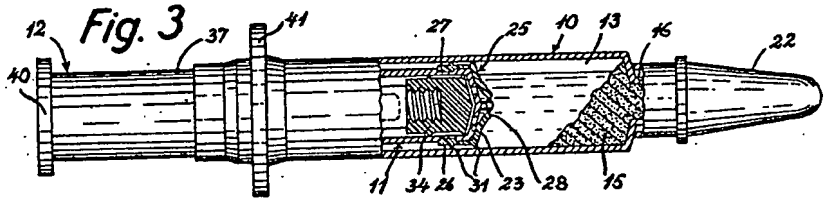

Fig. 4

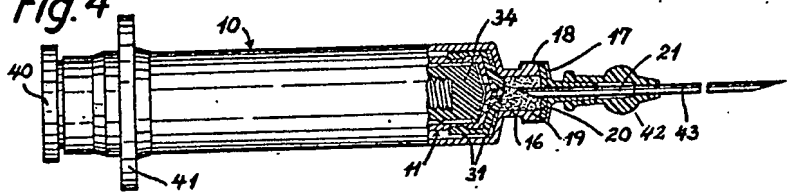

Fig. 5